

Section 7	510(k) Summary or 510(k) Statement
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Section 807.87 (h) A 510(k) Summary as described in Section 807.92 or a 510(k) statement as described in 807.93

Premarket Notification [510(k)] Summary as required by 21 CFR 807.92

Date summary was prepared:

June 2009

Submitter's Name:

.decimal, Inc.
121 Central Park Pl
Sanford, Florida 32771

Contact Person:

Daniel L. Bennett
Director of Quality and Regulatory Affairs
Phone: 407-330-3300
Fax: 407-322-7546
Email: dbennett@dotdecimal.com

Device Name:

Bolus Compensator

Classification Name:

IXI
21 CFR 892.5710
Class II

Predicate Device(s):

.decimal Range Compensator (K071078)



The benchmark for custom radiation therapy

Intended Use:

.decimal's Bolus Compensator manufacturing service manufactures the solid Bolus Compensators for intensity modulation of external beam radiation therapy. The Bolus Compensators are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Summary of Technological Characteristics:

The device features of Bolus Compensators are similar to the predicate device (.decimal Range Compensators K071078 cleared in 2007). They both are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. Whereas the Bolus Compensator is made using machinable wax, the Range Compensator is made using acrylic, despite the difference in materials they both share very similar densities. Like Range Compensators Each Bolus Compensator must be validated and approved by the radiation therapy professional prior to use on a patient. The target population is identical and the use parameters are also very similar.

A detailed comparison can be found in section 11 of this submittal.

Summary of Clinical Testing:

Clinical testing was not performed as part of the development of this product. Clinical testing is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Clinically oriented validation test cases were written and executed in house .decimal personnel including Board Certified Medical Physicists where Bolus Compensators was deemed fit for clinical use. A declaration of conformity to this requirement can be found in section 12 of this document.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2009

Mr. Daniel L. Bennett
Director of Quality and Regulatory Affairs
.decimal, Inc.
121 Central Park Pl.
SANFORD FL 32771

Re: K091911

Trade/Device Name: Bolus Compensator
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: June 24, 2009
Received: June 25, 2009

Dear Mr. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

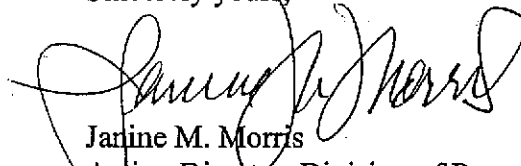
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jarline M. Morris", is written over the typed name.

Jarline M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 6	Indications for Use Statement
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510(k) Number (if known) K091911

Device Name: Bolus Compensator

Indication for Use: Bolus Compensators are used by radiation therapy professionals for the treatment of cancer patients. They are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. Each Bolus Compensator must be validated and approved by the radiation therapy professional prior to use on a patient.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091911